

EXHIBIT 15

CLAIM CONSTRUCTION SUMMARY

1. “Increased Level Of Anticomplement Activity”

Claim 1 requires that the solvent/detergent treatment of step a) result in an “increased level of anticomplement activity.” During claim construction, Plaintiffs argued that this term should be accorded its plain meaning. D.I. 160, pp.15-18.¹ Baxter argued that the term should be construed to mean, “increased anticomplement activity from a level *acceptable* for intravenous administration to a level *unacceptable* for intravenous administration.” D.I. 162, p.28 (emphasis added).² Baxter’s argument centered on improperly reading the word “unacceptable” into the claim term. *Id.* at pp.25-28. Thus, according to Baxter, step a) requires an increase in ACA to a precisely defined numerical elevation. *See id.* Baxter persists in this argument in its current motion. *See* D.I. 231, pp.24-25.³

The Court squarely rejected Baxter’s construction noting, “Defendants’ construction invited the court to import a limitation from the preferred embodiment into the claims.... Further, ‘nor may [the court], in the broader situation, add a narrowing modifier before an otherwise general term that stands unmodified in a claim.’” D.I. 199, p.2, n.4 (citation omitted).⁴ The Court, instead, accorded this term its plain and ordinary meaning in accordance with Plaintiffs’ proposed construction. *Id.* at p.2. Thus, under step a), ACA must simply increase, and this increase must be measurable.

¹ D.I. 160 is Plaintiffs’ Opening Claim Construction Brief.

² D.I. 162 is Defendants’ Opening Claim Construction Brief.

³ D.I. 231 is the Opening Brief in Support of Summary Judgment Motion Filed By Baxter International Inc. and Baxter Healthcare Corporation.

⁴ D.I. 199 is the Order Construing the Terms of U.S. Patent No. 6,686,191.

2. “Then Incubating The Solution of Step a)”

Claim 1 requires first treating a solution of antibodies with solvent/detergent in step a) and “then incubating the solution of step a)” to reduce the ACA to an acceptable level suitable for intravenous administration. During claim construction, the Court addressed whether this claim language allowed for additional processing steps between the solvent/detergent step (step a)) and the incubation step (step b)). Plaintiffs argued that the ordinary meaning of the claim language and the specification clearly allowed for additional processing steps before step b) and that the solution to be incubated was the solution originating from step a). D.I. 160, p.21. Baxter argued that there can be absolutely no intervening steps between step a) and step b). D.I. 162, p.29.

Accepting Plaintiffs’ proposed construction, the Court construed the term “then incubating the solution of step a)” to mean “incubating a solution originating from step a) under conditions of controlled time, pH, temperature, and ionic strength, wherein additional steps may be performed prior to said incubating,” D.I. 199, p.3; *see also id.* at n.6 (citing sections of the specification and noting that “to construe the claim terms as Defendants propose would be contrary to the specification”). Therefore, Claim 1 clearly permits intervening steps between step a) and step b), and the solution that is incubated under step b) is the solution that originates from step a).

3. “Increased Anticomplement Activity Of The Solution”

Claim 1 requires that the incubation of step b) reduce the “increased anticomplement activity of the solution.” During claim construction, Plaintiffs asserted that this claim term should be accorded its plain and ordinary meaning. D.I. 160, pp.23-24. Baxter argued that the term was indefinite because it is unclear to what “solution” this claim term refers. D.I. 162, p.29. In the alternative, pressing its discredited

“unacceptable” contention, Baxter argued that “increased” should be construed to mean “increased anticomplement activity of the solution from a level *acceptable* for intravenous administration to a level *unacceptable* for intravenous administration.” *Id.* (emphasis added). In other words, according to Baxter, the increased ACA has to be to a numerically defined “unacceptable” level.

Rejecting Baxter’s argument, the Court construed “increased anticomplement activity of the solution” in step b) to have its plain and ordinary meaning (D.I. 199, p.2), noting again that it is improper to add a narrowing modifier before an otherwise general term that stands unmodified in a claim (*id.* at n.5). Moreover, under the Court’s claim construction, the “solution” is the solution that is to be incubated, *i.e.*, the solution that originates from step a) and which may have been subjected to intervening process steps.

4. “Acceptable Level Suitable for Intravenous Administration”

At the end of the day, Claim 1 requires that the incubation of step b) reduce the ACA of the final container solution to an “acceptable level suitable for intravenous administration.” During claim construction, Plaintiffs asserted that this claim term should be accorded its plain and ordinary meaning. D.I. 160, p.24. Baxter argued the term was indefinite. D.I. 162, pp.34-38. In the alternative, Baxter argued that this claim term should be construed to mean “a defined numerical level that depends upon the protein concentration, specifically, 60 CH₅₀ units/mL for a 10% solution and 45 CH₅₀ units/mL for a 5% solution, as determined by the particular anticomplement activity assay used to obtain the anticomplement activity data reported in the ‘191 patent.” *Id.* at p.38.

The Court again rejected Baxter’s proposed construction, noting, “The Defendants’ alternative construction invites the court to import a limitation from the

preferred embodiment into the claims, which is contrary to Federal Circuit precedent....

Further, ‘when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims.’” D.I. 199, p.2, n.2 (citing *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998)). The Court construed “acceptable level suitable for intravenous administration” to have its plain and ordinary meaning. *Id.* at p.4.